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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,425	07/21/2003	Jeffrey Weitz	GLYCO-0012-C02	4953

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
KHARE, DEVESH	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,425	WEITZ ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/06/2006* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The applicant's remarks dated 10/10/2006 are acknowledged. The finality of the Office Action dated 4/10/2006 has been withdrawn. Claims 1-49 have been cancelled.

The objection and rejection under 35 U.S.C. 112, first paragraph and second paragraph of the office action dated 04/10/2006 is moot due to the cancellation of the claims. It is noted that applicant's terminal disclaimer over U.S. Patent 6,075,013 is applicable to instant claims 50-62.

During the course of reconsideration of the application, a prior art reference not previously disclosed by the applicants or the examiner came to light (see rejection below).

Claims 50-62 are currently pending in this application.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 50-62 are rejected under 35 U.S.C. 103(a) as being obvious over Bara et al. (Bara) (British Journal of Haematology, 1999, 104, pp 230-240) in combination with Zed et al. (Zed) (Arch. Intern Med/Vol, 159, Sep.13,1999, pp 1849).

Bara teaches the studies in experimental animal models and in patients receiving low molecular weight heparin (LMWH) to prevent throboembolic events after surgery and the ant-Xa and anti-IIa activities (abstract). Bara discloses the LMWH tinzaparin and enoxaparin of molecular weight of about 4500 Daltons (page 230, col.2, line 7). Furthermore, Bara discloses the anti-Xa activity after subcutaneous injection of enoxaparin in doses between 0.05-0.60 IU/ml (page 232, Fig.1) and the anti-IIa activities after subcutaneous injection of enoxaparin in doses between 0.02-0.12 IU/ml (page 233, Fig.2). Bara also discloses the anti-Xa and anti-IIa activities of LMWH tinzaparin and enoxaparin with or without deep vein thrombosis (page 235, Table VI and page 236, Table VII). Bara discloses that LMWHs are neither similar in terms of their molecular weight distribution, nor in terms of their anti-Xa/anti-IIa activities (page 237, col.1, lines 1-3). Bara's "LMWHs" can be used for treating a thrombotic condition in a mammal, however the prior art is silent in disclosing the LMWH having a molecular weight range between 5000-9000 Daltons.

Zed teaches the role of LMWHs in the management of patients with unstable angina or non-Q-wave myocardial infaraction caused by rupture of an atherosclerotic plaque, platelet activation, and fibrin deposition (abstract). Zed discloses that unfractionated heparin of molecular weight between 5000-30,000 Daltons effective to inactivate the co-agulation enzymes thrombin (factor IIa), factor Xa, and factor Ixa (page 1849, col.2, Unfractionated heparin, lines 1-13). Zed discloses that the LMWH having a molecular weight range between 4000-6500 Daltons have a reduced ability to catalyze the

inactivation of thrombin relative to their ability to catalyze the inactivation factor Xa (page 1850, col.3, low molecular weight heparins, lines 1-12 and Table 1). Furthermore, Zed discloses the clinical trials of LMWH in the doses such as 120 U/kg; 214 U/kg; and 1.0 mg/kg (page 1852, Table 3).

With regard to the very broad ranges of LMWH claimed of about 40 U/mg to 150 U/mg; and the molecular weight of LMWHs of 5400-8000 Daltons, 5800-7000 Daltons or 6000 daltons, it would be within the scope of the artisan in this art to optimize them through routine experimentation in the absence of unexpected results with a particular combination. With regard to the thrombotic conditions such as arterial thrombosis; venous thrombosis; pulmonary embolism; inhibiting thrombus formation, it would be within the inherent properties of LMWH to be effective in treating said conditions.

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to use the LMWH of Bara and Zed to treat thrombotic conditions of the instant claims where the inherent properties of the LMWH is beneficial in the treatment of a thrombotic condition or inhibiting the thrombus formation in a mammal because Bara and Zed references disclose that LMWHs are known to be used for the same method that is being claimed. Bara provides the motivation; the prior art suggests that LMWH are safe and effective against thromboembolic complications because of their greater bioavailability and a longer half-life than the unfractionated heparin (page 230, cols. 1 and 2).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. U.S. patent 4,942,156: Discloses Ester derivatives of low molecular weight heparin are disclosed. These derivatives exhibit improved Anti-Xa activity in relation to global anticlotting activity.

2. Bueller, H. R. : Discloses "s.c. administration of low-mol.-wt. heparin (LMWH) has been demonstrated to be as safe and effective for treatment of acute venous thrombosis as conventional treatment with unfractionated heparin, which requires i.v. infusion. In addn., LMWHs appear to provide an improved quality of life forpatients with less impairment of phys. activity. The ease of administration of LMWHs could be exploited in the clin. management of patients to increase the extent of LMWH outpatient therapy and reduce the no. of hospitalizations for venous thrombosis, thus providing a more cost-effective therapy than conventional heparin. Efficient support services, patient education and careful follow up will be required for home treatment to be successful."

3. Savage et al. : Discloses "upper extremity deep vein thrombosis (DVT) is now recognized as a major cause of morbidity and mortality. There is little information regarding the most effective treatment of this condition. The authors report a prospective cohort study of the use of low mol. wt. heparin (LMWH) in the outpatient management of upper extremity DVT. Patients were managed as outpatients for objectively documented upper extremity DVT with dalteparin (200 aXa u/kg), for a min. of 5 days. Warfarin was usually initiated on the 1st day with a target INR of 2.0-3.0. Most patients had an underlying malignancy or a history of a central line. All patients were followed for 12 wk from diagnosis. Only 1 patient had a major bleed. No patients developed pulmonary emboli. 1 Patient had a recurrence of DVT during the treatment with LMWH with extension of the existing thrombus. 7 Patients died, all due to their underlying disease. This study supports the safety and effectiveness of dalteparin in the treatment of upper extremity DVT. Given that these patients were treated as outpatients, there is a potential for huge cost savings.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
November 20, 2006

11/20/06
Anna Jiang, Ph.D.
Supervisory Patent Examiner
Technology Center 1600